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(54) Title of the invention: Thrombus Removal Means

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[1] Translator's note: Name of (72) and (74) not confirmed

SPECIFICATION

1. Title of the Invention
   Thrombus Removal Means

2. Claims
   (1) A thrombus removal means comprising the wire tip forming a shape-memory part composed of a shape-memory alloy, wherein at or below the transformation temperature, said shape-memory part is deformed plastically into a straight shape, and wherein said shape-memory part is restored to a shape capable of capturing a thrombus when heated to or above the transformation temperature.
   (2) The thrombus removal means described in Claim 1, wherein said shape-memory alloy is composed of a one-way shape-memory alloy and restored to a shape capable of capturing a thrombus at high temperatures.
   (3) The thrombus removal means described in Claim 1, wherein said shape-memory alloy is composed of a two-way shape-memory alloy, restored to a shape capable of capturing a thrombus at high temperatures, and restored to the straight shape at low temperatures.
   (4) The thrombus removal means described in Claim 1, wherein said shape-memory alloy is composed of a Ni-Ti alloy.

3. Detailed Explanation of the Invention
   [Field of Industrial Application]

The present invention relates to a thrombus removal means that removes an intravascular thrombus.

[Prior Art]

A popular method of removing an intravascular thrombus generally is one that uses a balloon catheter (*New Cardiac Catheterization Techniques*, Imano et al., published by Nankodo). This method uses a stylet when a catheter is inserted. Also, physiological saline solution is infused via the catheter to blow up the balloon.

[Problems That the Invention Is to Solve]

In the aforementioned catheterization method, when the catheter is inserted, it is necessary to use a stylet, resulting in a complex structure. Also, the aforementioned balloon is composed of an extremely thin film, so there is some risk of bursting when it is overfilled with physiological saline solution. To eliminate this risk, close attention must be paid to the operation that regulates infusion at a certain amount or below when infusing physiological saline solution, so this operation is troublesome.

Also, recently the clot removal operation sometimes is performed while checking the position and state of a clot by using a vein endoscope. However, the aforementioned catheter has a large outside diameter and a larger-diameter channel for endoscope insertion is required, so the endoscope insertion part also necessarily is limited to thick veins.

The present invention was developed while focusing on the aforementioned problems, and its purpose is to provide a thrombus removal means that has a simple structure, that is simple to operate, that enables the safe removal of a thrombus, and that enables insertion into finer vessels.

[Means of Solving the Problems]

A thrombus removal means such that the wire tip forms a shape-memory part composed of a shape-memory alloy; and having a memory such that, at or below the transformation temperature, this shape-memory part is deformed plastically into a straight shape; and by heating [it] to or above the transformation temperature, [it] is restored to a shape capable of capturing a thrombus.

[Operation of the Invention]

When inserted into a blood vessel, the shape-memory part of a wire deforms plastically into the straight shape. By heating its shape-memory part after [it] is inserted into the blood vessel, it is restored to a shape capable of capturing a thrombus, enabling [it] to capture the thrombus.

[Embodiments]

The first embodiment of the present invention is shown in Figures 1 through 5.

In Figure 1, 1 is the vein endoscope. In this endoscope 1, a branching part 3 is provided at the end of the flexible insertion part 2, and connected to this branching part 3 ~~are an observation cable 4 housing an image guide fiber and a light guide cable 5 housing~~ a light guide fiber. The eyepiece 6 is provided at the extended end of the observation cable 4. Also, a connector 7 is provided at the extended end of the light guide cable 5, and this connector 7 is detachably connected to a light source for illumination 8.

Furthermore, at the aforementioned branching part 3 are provided a channel opening 12 with a cock and an infusion opening 13, both of which are connected to the same channel 10. An infusion tube 14 is connected to the infusion opening 13, and a syringe 15 for infusion of the physiological saline solution is connected detachably to this infusion tube 14. Also, a channel 11 different from the aforementioned channel 10 also is formed in the endoscope 1. Both channels 10 and 11 are formed along the entire length within the insertion part 2, and [they] open at the end surface 16 of the insertion part 2, as shown in Figure 2 and Figure 3. Furthermore, at the end surface 16 of this insertion part 2

are provided an objective lens 17 connected to the aforementioned image guide fiber and an illumination window 18 connected to the light guide fiber.

On the other hand, the thrombus removal means 20 inserted into a blood vessel via the channel 10 of this vessel endoscope 1 is configured as follows. That is, [it] is composed of a wire 21 inserted through the aforementioned channel 10, and this wire 21 is composed of a shape-memory alloy (e.g., an Ni-Ti alloy). Furthermore, as shown in Figure 3 and Figure 4, the end part 22 of the wire 21 is bent into a conical coil shape and, as mentioned hereinafter, heat-treated in a filter shape capable of capturing a thrombus 27, to make it remember this shape. In this state, the Ni-Ti alloy forms the bicrystalline martensitic phase (high-temperature phase)[2]. Also, the finish temperature A_f point at which there is metamorphosis to the austenitic phase is set within a range of 40 °C to 42 °C. Regarding this end part 22, an external force is exerted at room temperature (e.g., 25 °C), and, as shown in Figure 2, it forms a straight shape. At this time, the Ni-Ti alloy forms the deformed martensitic phase (low-temperature phase).

Also, at the base end of the aforementioned wire 21 is attached an operation knob 23, as shown in Figure 1.

Next, the usage of the aforementioned thrombus removal means 20 will be explained. First, as shown in Figure 5, an incision is made in the patient's femoral region to expose the femoral artery 25. Then this is incised and the insertion part 2 of the vein endoscope 1 is inserted via this incised portion 26. The endoscope 1 is used to find a thrombus 27 within the femoral artery 25. Therefore, after the end surface 16 is moved near the thrombus 27, as shown in Figure 2, the wire 21 of the thrombus removal means 20 is inserted via the channel opening 12. Furthermore, at this time, the end part 22 of the wire 21 is deformed into the straight shape by applying an external force at low room temperature.

The wire 21 inserted via the channel opening 12 is guided via the channel 10, and as shown in Figure 2, its end part 22 is projected toward the thrombus 27. At this time, the end part 22 is straight, so it easily penetrates the thrombus 27. Next, the syringe 15 is connected to the infusion tube 14, and physiological saline solution heated to at least 40 °C to 42 °C is infused, thereby infusing [it] into the femoral artery 25, via the gap between the wire 21 and the channel 10. This physiological saline solution is used to heat the end part 22 of the wire 21, and by raising [the temperature] to at least the transformation temperature A_f point, [it] is bent into the memorized conical coil shape as shown in Figure 3, resulting in a filter shape capable of capturing the thrombus 27.

Then, as shown in Figure 4, the wire 21 is retracted to make its conical coil-shaped end part 22 contact the thrombus 27, and [it] is retracted together with the thrombus 27.

[2] Translator's note: This seems to be mistaken. The martensitic phase is the low-temperature phase, while the austenitic phase is the high-temperature phase.

After this is moved to the incised part 26 of the femoral artery 25, tweezers 28 are used to removed [it] from the incised part 26, as shown in Figure 5.

The second example of the present invention is shown in Figure 6. The present embodiment differs from the first embodiment only in that the memorized shape of the end part 22 of the wire 21 is a spiral.

The third embodiment of the present invention is shown in Figure 7. The present embodiment differs from the first embodiment only in that the shape memorized in the end part 22 of the wire 21 is a single ring.

The fourth embodiment of the present invention is shown in Figure 8. The present embodiment differs from the first embodiment only in that the shape memorized in the end part 22 of the wire 21 is a coil.

The fifth embodiment of the present invention is shown in Figure 9. In the present embodiment, the shape memorized in the end part 22 of the wire 21 is a mesh. Furthermore, this thrombus removal means 20 is housed within a sheath 29 made of a synthetic resin (e.g., Teflon). In this case, [it] is used with this sheath 29 instead of the endoscope 1, and the physiological saline solution for heating is infused via the gap between the wire 21 and the sheath 29.

In addition, the x-ray-based fluoroscopy is used to check the positions of the wire 21 and the thrombus 27 in this case.

Furthermore, examples of the use of the thrombus removal means 20 of the present invention are not limited to using a straight-shaped end part 22 to pierce a thrombus 27. When a thrombus adheres to a vessel wall, for example, [it also is possible] to scrape off the thrombus by moving back and forth the end part restored to its memorized shape, collect the thrombus, and remove it from the body. Or the residual part of a thrombus that has been scraped off [could] be aspirated off by using the endoscope channel.

Furthermore, the thrombus removal means of the present invention can be used to collect and remove from the body the residual part of a laser-treated thrombus.

Also, the method used to heat the end part of the wire is not limited to that of the aforementioned embodiments. For example, it also is possible to heat at high frequency from outside the body. In addition, heating also can be performed by pulsing a current in part of the wire, for example, and then using this resistance heat. According to the pulsed current method, it is possible to control the speed of the change in shape of the end part, by means of pulse width modulation, etc. Also, this current heating part also may be configured on the [user] side of the aforementioned sheath 29. Moreover, it also is conceivable to heat by means of the body temperature after wire insertion.

Furthermore, the material of the wire of the thrombus removal means is not limited only to the aforementioned Ni-Ti alloy. For example, [any alloy] (e.g., a Cu-Zn-Al alloy) may be used as long as it exhibits the shape-memory effect. Also, it also is possible to use a shape-memory alloy to form only the end part of the wire. Furthermore, the shape-

memory alloy is not limited to a one-way [shape-memory alloy], and [it] can be a two-way (i.e., bidirectional) [shape-memory alloy]. In this case, memory is given such that [it] assumes a shape capable of capturing a thrombus on the high-temperature side, and [it assumes] a straight shape on the low-temperature side. A straight shape can be formed by, for example, feeding cold water before inserting [it] into a blood vessel.

Also, the [configuration] may be such that a balloon is provided at the periphery of the tip of the aforementioned endoscope or sheath, so that [the vessel] can be treated while blocking the flow of blood by inflating this balloon to close the vessel midstream.

[Effects of the Invention]

As explained previously, the thrombus removal means of the present invention has a simple wire-shaped configuration, thereby enabling miniaturization. Merely by inserting [it] into a blood vessel and heating its end part, it is possible to restore its memorized shape, so operation is simple and [it] can be used safely.

4. Brief Explanation of the Drawings

Figure 1 is a general configuration diagram of the first embodiment of the present invention. Figures 2 through 5 are perspective views showing the operating procedures of this embodiment. Figures 6 through 9 are perspective views of the second through fifth embodiments, respectively.

20 Thrombus removal means
21 Wire
22 End part
25 Femoral artery
27 Thrombus

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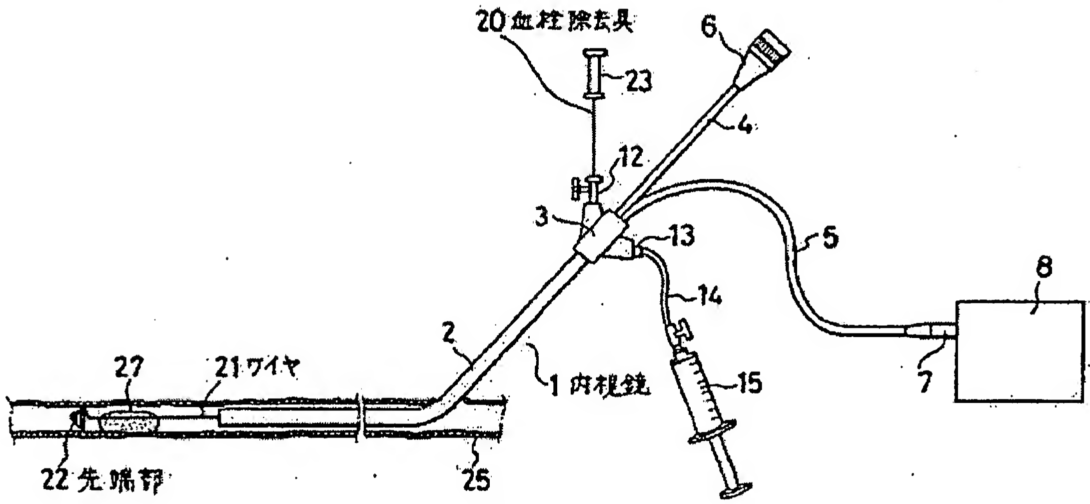

Figure 1

Key
1 Endoscope
20 Thrombus removal means
21 Wire
22 End part

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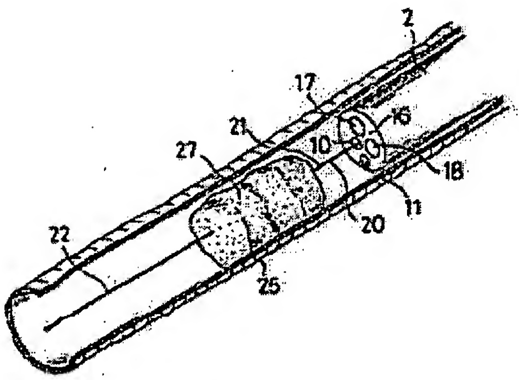

Figure 2

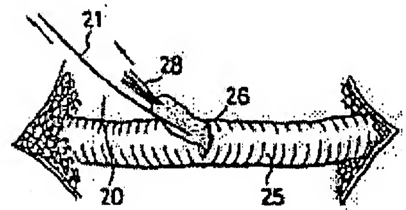

Figure 5

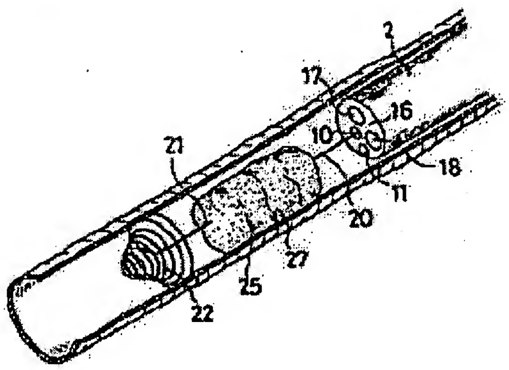

Figure 3

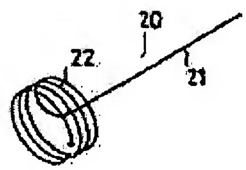

Figure 6

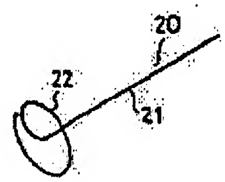

Figure 7

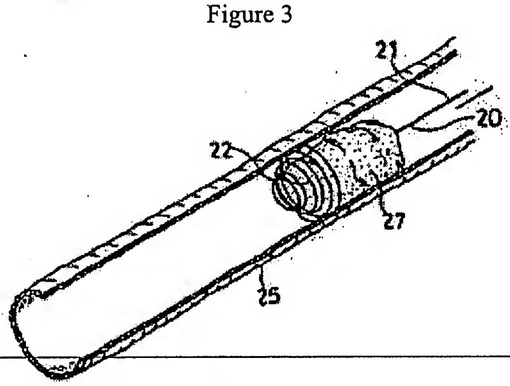

Figure 4

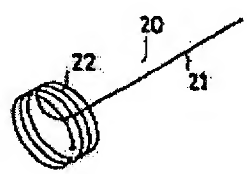

Figure 8

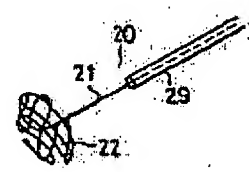

Figure 9

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CERTIFICATION OF ACCURACY

I CERTIFY, UNDER PENALTY OF PERJURY UNDER THE LAWS OF THE UNITED STATES OF AMERICA THAT WE ARE COMPETENT IN **ENGLISH** AND **JAPANESE** AND THAT THE FOLLOWING IS, TO THE BEST OF OUR KNOWLEDGE AND BELIEF, A TRUE, CORRECT, COMPLETE AND ACCURATE TRANSLATION OF THE ORIGINAL **DOCUMENT WHICH WE'VE REVIEWED, REGARDING DECISION OF FINAL REJECTION FOR PATENT H9-527922.**

MAY 17, 2007

Mariam Nayiny

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